



MEDI-CAL DRUG USE REVIEW BOARD

Timothy Albertson, Chairman
Janeen McBride, Vice-Chairman

Stephen Stahl
Kenneth Schell

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SEPTEMBER 2003 DUR BOARD MINUTES

Roll Call and Guests: Called to order. Present: Dr Albertson, on phone: Dr Wong, Dr Schell, Dr Stahl; absent Dr Jones, Ms McBride. Board has a quorum. **Staff:** Dr Simon-Leack (EDS), Mr. Vic Walker (DHS), Dr Kevin Gorospe (DHS), Dr Ron Sanui (DHS), Veronica Zepeda (DHS), Sherri Price (EDS). **Guests:** Welyn Bui (Lilly), Wendy Fong (Abbott labs), Rodger Powers (Bristol Myers), Jeffrey Hille (Lilly), Angela Jones (Aventis), Jennifer Rice (Aventis), Christy Gorham (Organon), Sadie Heller (Janssen), Anne Judson (AWARE), Elissa Maas (AWARE), Tammy Chang (PCN).

Approval of Minutes: Motion to approve as written (Dr. Albertson). No discussion. Approved unanimously.

Announcements: Dr. Schell has recently been appointed to the California State Board of Pharmacy.

Operational Topics:

1. **Dr Gary McCart** has notified the Board that he is retiring from practice and from the DUR Board, effective immediately.
2. **Board Membership/Board Term Changes** – Mr. Walker stated that the DUR Board lacks a standard mechanism for managing terms of membership and he developed the following text which proposes certain changes. These are still under consideration by the State. “There should be a total of 8 Board members, four physicians and four pharmacists who shall serve staggered four year terms or until their respective successors shall join the Board. During the initial implementation, two members shall be eligible to be replaced every year without regard to their initial start of service. Board members shall be eligible for reappointment for an additional four year term at the pleasure of the Director and the agreement of the Board member.” The longest serving Board members would be rotated off next, which would be Dr. Albertson and Ms McBride. Mr. Walker asked for Board input on this topic. Board members supported these changes. Comment included that the process to acknowledge retiring board members needs to be standardized and timely. Additionally, one four year term represents a total of 16 meetings, and if a Board member is retired at this point, the risk is that there is a loss of institutional knowledge and leadership. The Director’s discretion can act to modify the term limit by renewing the

member's term. Dr. Wong added that the most senior members should not be rotated off at the same time. He suggested that the chairperson should be assigned an intermediate role, such as Chair Emeritus for perhaps two years so as to retain the knowledge of a senior member while undergoing transition.

3. Electronic Meeting Formats - Videoconferencing, NetMeeting, etc. – Mr. Walker revisited the topic of electronic meeting formats. The new state facility has videoconferencing capacity and he strongly encouraged Board members to explore their own institution's resources in this respect. Dr Simon-Leack added that electronic communication is likely to become standard in the future and it behooves us to explore our resources as a Board now. Dr Schell stated Kaiser has videoconferencing capacity. Dr Wong will explore his facility's resources. Videoconferencing is not a computer-based tool and does not run afoul of firewall security issues. NetMeeting is a computer-based tool that is a part of most Windows systems newer than the Windows '98 version and allows materials to be illustrated on all meeting attendees' computer screens simultaneously.

Disease Management/Project Update Discussion –

Mr. Walker introduced Dr Ron Sanui, a pharmacist now working with Medi-Cal policy division, having transferred from the Managed Care component of Medi-Cal. Mr. Walker also introduced Dr Greg Doe, a pharmacist who has joined Medi-Cal policy from the General Services Department. These two individuals bring considerable knowledge to the Department.

Step Therapy - refers to a process that could be characterized as an electronic prior authorization process. A drug claim would be evaluated as to whether it meets certain conditions of use before being paid. An example is a claim for a COX2 inhibitor. The beneficiary's profile would be queried for use of broader NSAIDs such as ibuprofen or Naprosyn, which should be first line drugs in this category. If there is no evidence of use, then the claim would be denied with the specification that more appropriate choice of therapy should be used first.

Q: Would there be any clear explanation of the denial?

A: A limited amount of information could be sent back, such as "does not meet criteria" with the criteria spelled out in the manual or other document.

Q: What disease states are targeted?

A: Currently only COX II inhibitors but will very likely be expanded.

Discussion: Quality of information sent back to pharmacy will affect whether this program is successful in its goals or simply a burden on the pharmacy. A concern was expressed that this activity be designed so that it will not frustrate providers and hinder care. Many efforts at step care therapy have been attempted in different systems and the results are not always favorable. Some consideration needs to be made for the knowledge of specialists – rheumatologists are more likely to use COX II inhibitors appropriately and building this into the step care protocol is important. Grady Health Care systems chose to remove the COX II inhibitors from their formulary altogether, which is very counterproductive to good care. DHS plans to work toward making the messaging as effective as the communications standards and technology permit. It is believed that designing an electronic step care therapy rather than simply placing these drugs into a prior authorization should smooth out and speed up the processing of

these claims. The more that electronic decision making can assist processing of drug claims, the faster claims should be adjudicated. The SCORE algorithm may not be the optimal design but Dr Schell may be able to provide an algorithm with some useful features.

Physician Interaction and Feedback –The DUR program is trying to build an effective tool of communication with physicians in a peer-to-peer approach, emphasizing collegiality rather than an adversarial relationship. DHS may be hiring a staff including a physician, pharmacist and research/data analysts to assist in addressing some of the prescribing practices more directly and may even result in face-to-face contacts to provide information. Mr. Walker requested that Board members forward any examples of physician feedback documents. The Atypical Antipsychotic Education Project (AAEP) is evaluating the use of county mental health directors to assist in this process. One element of effective intervention is a current knowledge of trends of practice.

Enhanced Educational Programs – Along the same ideas of physician feedback but recognizes that traditional approaches to education are unlikely to produce the type of change necessary to impact our system. Therefore more creative and original formats need to be employed. Mr. Walker asked if Dr Stahl could retrieve the numbers of physicians responding to the CME for the AAEP. Dr Stahl replied that he would request his staff to do so and return this information.

ATYPICAL ANTIPSYCHOTIC EDUCATION PROJECT

Mr. Walker described the efforts of this project as excellent examples and a potential template for further disease management activities. Dr Stahl added that this project has been striving to provide education in a creative format and follow up that education with methods that reinforce the message and provide feedback to the provider. The focus is managing how a drug is used, not restricting or eliminating availability of the drug. Besides step therapy, edits that regulate polypharmacy can be used to direct appropriate use. Since this project may act as a template, the possibility of building closely related activities into this project exists. Diabetes has been mentioned in the past and is still a strong candidate for this type of expansion.

Dr Stahl provided a brief update of the project, mentioning the two main foci of the project currently are the expansion of the use of the project algorithm/guideline and development of physician feedback tools that would be piloted in select county mental health departments. The goal is to reduce low evidence, high cost practices. Additionally, an analysis has been completed of an IMS audit regarding appropriate use of anticonvulsants in both bipolar and schizophrenia disorders. Development of feedback tools not only includes pilot projects with county mental health directors but a program in San Diego (November and December 2003) designed to both educate and control the outlying prescribing practices. This program will be followed up by a phone contact and a lunchtime contact. Analysis of the outcome of this activity should be complete by the end of January 2004. Contact has also been made with all the county mental health directors in two instances and they are very supportive of the program. Dr. Stahl also reported that the International Algorithm Committee (of the European College of Neuropsychopharmacology) has incorporated substantial elements of the AAEP algorithm in their efforts to build and roll out algorithms in the treatment of schizophrenia throughout the world. **A larger goal would be to cast the DUR Board and program as a resource for best practices.**

AWARE

Ann Judson from the AWARE program briefly described some of the current AWARE activities and directions. She distributed a draft of a clinical compendium developed by the AWARE group for the treatment of upper respiratory tract infections for both adults and children. Distribution of this compendium will be followed by CME to strengthen the information contained in the compendium. The compendium is a collection of best practices in the state of California developed by leaders in the field and supported by affected organizations throughout the state. In addition to the compendium, a large data collection and reporting project is moving forward, collecting data related to incidence and treatment of upper respiratory tract infections from the year 2000 forward. Every major health care provider is participating in this and the resulting report will provide a rare and comprehensive look at this element of health care in California. The DUR Board is working closely with AWARE and this data project will include Medi-Cal data. AWARE has a website at www.aware.md

ARTHRITIS

Dr. Wong noted that this project is still in the midst of raising funds since the National Arthritis Foundation scaled back its funding of proposals. Funding from the state is also being looked at but currently it is not available. During the fundraising period, effort is also being made to refine the project design. To do this, he needs a small dataset of claims data with similar parameters to the full sized version. Mr. Walker will explore how to provide this. Industry is also being approached for assistance

DIABETES – A program is being considered that would start with exploring diabetes in the schizophrenic and bipolar populations, using data from the AAEP and eventually becoming full scale. Prior to doing this, some contacts will be made with current activities outside of DUR involving CphA and Katherine at DHS to see how we can insure our combined cooperative efforts. Mike Negretti has already been contacted. Dr Sanui recommended contact with Medi-Cal managed care, as they have been involved with projects in both diabetes and asthma. Important to avoid building large stand alone disease management programs because people do not have stand-alone disease. Co-morbidities are the nature of most individual's health profile and a disease management approach that recognizes this will have much more chance of success than one that does not.

PAIN MANAGEMENT – This is a topic discussed at previous Board meetings and is driven by the difficulty of understanding appropriate prescribing of narcotics. The Department of Justice has expressed a keen interest in some guideline or standard of prescribing but starting up an activity of this nature is difficult. An alternative mentioned at the last Board meeting is a program being put on by Dr Stahl and the Neuroscience Education Institute, along with the University of California, San Diego. It is a four-day psychopharmacology congress, which will be held in different cities in different years. It has five tracks for mental health professionals, one being for pain. It will be held in March in 2004. All physicians in California must have 12 hours of pain-related continuing medical education by 2006 to keep their licenses current.

Brief Reports

Mr. Walker reported that he had been trying for some time to smooth the process of data sharing with Board members to allow faster development of data analysis activities. This has taken a great deal of time but following a recent contact with the legal department, Mr. Walker will be meeting with a legal department staff to finalize a data agreement.

On-going Business

Redesign of the Target Drug List – Jude suggested that this be deferred to a later date when the Disease Management planning for the DUR program is completed. Designing a functional target drug list requires some well defined guiding principle or the list will become unmanageably large. Furthermore the process of interpreting the patterns of alerts and overrides depends on a clear philosophy behind these alerts.

Early Refill Alert -Early refill alert continues to screen all formulary file drugs submitted for payment. Since this alert was expanded to all drugs, the number alerts overridden has gone DOWN. Which means more claims relative to the alerts are being denied by the pharmacist because of the request being too early.

Packet Reports - First DataBank clinical information (attachment One) – summary of the past nine months shows very little new information that is ordinarily brought to the Board. Dr. Simon-Leack will continue to bring the relevant information to the Board.

The report related to number of monthly alerts shows a relatively unchanging pattern. While the number of alerts seems high overall, there have been no provider complaints regarding the alert volume. (attachment Two)

NEXT BOARD MEETING – NOVEMBER 17, 2003.

Meeting adjourned at 11:50 a.m.

SEPTEMBER 2003 BOARD MINUTES

CALIFORNIA DEPARTMENT OF HEALTH SERVICES PROSPECTIVE DUR ALERT SUMMARY BY THERAPEUTIC PROBLEM TYPE (P11)

AUGUST 2003

STATEWIDE ELIGIBLES : 3,046,155
STATEWIDE DRUG CLAIMS : 6,357,772
STATEWIDE DUR DRUG USERS : 1,132,274
STATEWIDE DUR DRUG CLAIMS: 4,730,989

STATEWIDE DUR DRUG ALERTS: 1,212,981
STATEWIDE OVERRIDES : 842,840
STATEWIDE CANCELLATIONS : 532

| THERAPEUTIC PROBLEM TYPE | NUMBER OF ALERTS | ALERTS% OF DUR DRUG ALERTS | ALERTS / 1000 DUR DRUG CLAIMS | ALERTS / 1000 DUR DRUG USERS | ALERTS / 1000 DRUG CLAIMS | ALERTS / 1000 ELIGIBLES | NUMBER OF OVERRIDES | OVERRIDES/ 1000 ALERTS | NUMBER OF CANCELS | CANCELS / 1000 ALERTS |
|--------------------------------|---------------------|----------------------------------|--|---------------------------------------|------------------------------------|-------------------------------|------------------------|------------------------------|----------------------|-----------------------------|
| DRUG-DRUG | 7,237 | .59 | 1.52 | 6.39 | 1.13 | 2.37 | 5,842 | 807.24 | 3 | .41 |
| HIGH DOSE-AD | 58,888 | 4.85 | 12.44 | 52.00 | 9.26 | 19.33 | 41,884 | 711.24 | 15 | .25 |
| HIGH DOSE-PD | 15,716 | 1.29 | 3.32 | 13.88 | 2.47 | 5.15 | 11,262 | 716.59 | 3 | .19 |
| TOTAL HD | 74,604 | 6.15 | 15.76 | 65.88 | 11.73 | 24.49 | 53,146 | 712.37 | 18 | .24 |
| LOW DOSE -AD | 60,842 | 5.01 | 12.86 | 53.73 | 9.56 | 19.97 | 42,862 | 704.48 | 17 | .27 |
| LOW DOSE -PD | 7,359 | .60 | 1.55 | 6.49 | 1.15 | 2.41 | 5,286 | 718.30 | 0 | 0.00 |
| TOTAL LD | 68,201 | 5.62 | 14.41 | 60.23 | 10.72 | 22.38 | 48,148 | 705.97 | 17 | .24 |
| EARLY REFILL | 345,066 | 28.44 | 72.93 | 304.75 | 54.27 | 113.27 | 189,716 | 549.79 | 285 | .82 |
| LATE REFILL | 191,173 | 15.76 | 40.40 | 168.83 | 30.06 | 62.75 | 153,716 | 804.06 | 51 | .26 |
| INCORR DUR | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| DRUG-ALLERGY | 764 | .06 | .16 | .67 | .12 | .25 | 569 | 744.76 | 0 | 0.00 |
| DRUG-DISEASE | 28,297 | 2.33 | 5.98 | 24.99 | 4.45 | 9.28 | 21,030 | 743.18 | 0 | 0.00 |
| DRUG-GENDER | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| DRUG-PREG | 11,397 | .93 | 2.40 | 10.06 | 1.79 | 3.74 | 8,252 | 724.05 | 3 | .26 |
| THERAPY DUP | 263,866 | 21.75 | 55.77 | 233.04 | 41.50 | 86.62 | 193,232 | 732.31 | 75 | .28 |
| INGRED DUP | 162,645 | 13.40 | 34.37 | 143.64 | 25.58 | 53.39 | 119,201 | 732.89 | 55 | .33 |
| DRUG AGE | 245 | .02 | .05 | .21 | .03 | .08 | 162 | 661.22 | 1 | 4.08 |
| ADDITIVE TOX | 59,486 | 4.90 | 12.57 | 52.53 | 9.35 | 19.52 | 49,826 | 837.60 | 12 | .20 |
| TOTAL | 1,212,981 | | | | | | 842,840 | | 532 | |

**FIRST DATA BANK DRUG-DRUG INTERACTIONS – SEVERITY LEVEL ONE –
AND DOSAGE CHANGES – SUMMARY FOR DUR BOARD SEPT 2003**

| DRUG DRUG INTERACTION | EFFECT OF INCOMING (FORMER) DRUG | EFFECT OF DRUG ON PROFILE (LATTER DRUG) |
|--|---|--|
| Rosuvastatin - Cyclosporine | increased effect of the former drug | increased effect of the latter drug |
| Eletriptan/Nefazodone | increased effect of the former drug | increased effect of the latter drug |
| Agalsidase Beta/Chloroquine | decreased effect of the former drug | decreased effect of the latter drug |
| Agalsidase Beta/Amiodarone | decreased effect of the former drug | decreased effect of the latter drug |
| Agalsidase Beta/Monobenzene (Benoquin) | decreased effect of the former drug | decreased effect of the latter drug |
| Agalsidase Beta/Gentamicin | decreased effect of the former drug | decreased effect of the latter drug |
| Penicillamine/Oxy-Phen; Phenylbutazone | adverse reactions of both drugs | adverse reactions of both drugs |
| Penicillamine/Antimalarial Agents | adverse reactions of both drugs | adverse reactions of both drugs |
| Vardenafil/Indinavir; Ritonavir | increased effect of the former drug | increased effect of the latter drug |
| Vardenafil/Itraconazole; Ketoconazole | increased effect of the former drug | increased effect of the latter drug |
| Pimozide/Aprepitant | adverse reaction of the former drug | adverse reaction of the latter drug |
| Astemizole; Terfenadine/Aprepitant | adverse reaction of the former drug | adverse reaction of the latter drug |
| Cisapride/Aprepitant | adverse reaction of the former drug | adverse reaction of the latter drug |
| | | |
| DRUG AND STRENGTH | DOSAGE RANGE | |
| Celexa 10mg tabs | with a range of 20-40mgday | |
| Opium tincture 10% | 0.3-6mlday. | |
| Lovenox 30mg/0.3ml ampule | with a range of 30-60mgday. | |
| Allegra 30 mg tab | with a range of 30-120mg/day | |